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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re the Application of:

MARRACK et al.

Serial No.: 09/844,928

Filed: April 26, 2001

Atty. File No.: 2879-76

For: "PRODUCT AND PROCESS FOR
REGULATION OF T CELL
RESPONSES"

Group Art Unit: 1644

Examiner: Ewoldt, G.

RESPONSE TO
RESTRICTION REQUIREMENT

EXPRESS MAIL: EV331285080US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This response is filed in response to the Restriction Requirement having a mailing date of July 1, 2003. This response is believed to be timely and therefore, no fees are enclosed. In the event that fees are due in connection with this response, please debit Deposit Account No. 19-1970.

The Examiner has restricted the claims of the invention into 23 groups. The claims are essentially divided on two bases: (1) on the basis of reagents that could be used to increase IL-15 activity and reagents that could be used to decrease IL-2 activity; and (2) on the basis of the methods of use of the compositions. Applicants elect, with traverse, to prosecute the claims of Group II (Claims 1-3, 9 and 14-17), directed to a vaccine adjuvant and a vaccine, wherein the adjuvant comprises IL-15 or an IL-15 homologue and an agent that binds to IL-2 and blocks or prevents the interaction of IL-2 with an IL-2 receptor.

Applicants traverse the restriction between Groups I-XX and through any of these product groups and the method groups XXI-XXII. The Patent Office may require restriction if two or more "independent and distinct" inventions are claimed in one application. However, "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." M.P.E.P. Section 803.

First, with regard to Groups I-XX, Applicants submit that a thorough search for Group II should also include the subject matter of Groups I and III-XX. In the present case, the subject matter of these Groups cited by the Examiner is sufficiently small and is so closely related as to be capable of examination together. The invention is directed to the concept that increasing the activity of IL-15 and decreasing the activity of IL-2 is useful for increasing a memory T cell response. The compounds recited in Claim 1 together achieve this goal. Applicants submit that the Examiner has merely selected from various preferred embodiments of the invention in order to facilitate a search, but if the concept of the invention is carefully searched, it is submitted that the groups are capable of examination together without any undue burden on the Examiner. To ask Applicants to file 23 different applications to cover the invention presented in the application is to place an unreasonable burden on Applicants.

Moreover, many of the groups appear to overlap given the manner in which they are divided. For example, comparing the election of IL-15 or a homologue thereof in Groups II, VII, XII, and XVII with the equivalent component in Groups I, VI, XI, and XVI (i.e., an agent that binds to an IL-15 receptor), it is submitted that IL-15 or a homologue thereof is an agent that binds to an IL-15 receptor, and therefore, given the overlap, it is improper to divide the claims on this basis. Moreover, comparing the election of an agent that binds to and blocks the interaction of IL-2 with an IL-2 receptor in Group II and similar groups with the agents that block or decrease IL-2 receptor activity in Group XI and similar groups also constitutes an overlap, since an agent that belongs in Group II could also belong in Group XI. Therefore, at a minimum, Applicants respectfully request that the Examiner withdraw the restriction between the elements as set forth above and rejoin many of the product groups with Group II or restructure the restriction requirement to more reasonably cover the invention.

With regard to the method claims of Groups XXI and XXII, if the elected claims of Group II and any rejoined product groups are found allowable, Applicants reserve their right to amend the claims of Group XXI or XXII to be commensurate in scope with the product claims of Group II, and to request that such amended method that depend from or otherwise include all the limitations of the allowable product be rejoined and examined for patentability. In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996); In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995).

In summary, the restriction requirements in this case only serve to increase the prosecution expense to the Applicants and to the Patent and Trademark Office. Applicants respectfully request that the Examiner withdraw the restriction requirements as discussed above.

Respectfully submitted,

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